



Food and Drug Administration
10903 New Hampshire Avenue
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April 13, 2015

El. En. Electronic Engineering S.p.A.
Mr. Paolo Peruzzi
Regulatory Affairs Manager
17 Via Baldanzese
Calenzano 50041
Italy

Re: K150516
Trade/Device Name: DEKA SYNCHRO REPLA:Y family of Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic
surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 13, 2015
Received: March 18, 2015

Dear Mr. Paolo Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

K150516

Device Name

Deka Synchro Repla:Y family of laser systems

Indications for Use (Describe)

755nm laser:

Temporary hair reduction.

Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

On all skin types (Fitzpatrick I – VI) including tanned skin.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

Photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

1064nm laser:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB . The lasers are indicated on all Skin Types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins.

Coagulation and hemostasis of soft tissue.

Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.

The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

Pulsed light FT handpiece:

Permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

Different wavelength ranges of Pulsed Light attachment are indicated for the various treatments and skin types, as indicated in the following table:

Pulsed light Wavelength range	Hair reduction	Vascular lesions	Blood vessels	Pigmented lesions
500-1200nm	-	Skin Types I, II	Skin Types I, II	-
520-1200nm	-	Skin Type III	Skin Type III	Skin Types I, II
550-1200nm	Skin Types I, II	-	-	Skin Type III
600-1200nm	Skin Type III	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary**K150516****Deka Synchro Repla:Y family of Laser Systems – Special 510(k)****Submitter:**

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Contact:

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Date Summary Prepared:

April 9, 2015

Device Trade Name:

Deka Synchro Repla:Y family of Laser Systems

Common Name:

Medical Laser and pulsed Light system

Classification Name:

Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (GEX)

Classification Number:

21 CFR 878.4810

Equivalent Devices:

DEKA Synchro Repla:Y family of laser systems (K131095).

Device Description:

The Deka Synchro Repla:Y family of lasers is a platform which can be equipped with two separate solid state laser heads (755nm and 1064nm) and a pulsed light handpiece (FT handpiece).

The two laser heads can only be activated separately and they deliver the laser output through the same single laser delivery system, consisting of a lens coupled user replaceable optical fiber with a wide range of interchangeable, quick release laser handpieces with electronic spot recognition.

The FT handpiece delivers the pulsed light to the treatment area by means of a sapphire lightguide; it is provided with has an integrated skin cooling system and is equipped with five different emission spectra interchangeable filters.

The system allows to switch from one of the three available sources to the other by pressing a key on touch panel.

Handpiece activation is either by footswitch or fingerswitch.

The modifications to the device are two laser handpieces, allowing for a larger treatment area, 22mm and 24mm, and a change of maximum pulse repetition rate for some intermediate settings for the Nd:YAG laser source.

The device hardware did not require any modification to support the new features. Minor changes to the software have been made in order to manage the new handpieces and the modified intermediate settings for the Nd:YAG laser source.

The intended use of the modified device, as described in the labeling, has not changed as a result of the modifications.

Intended Use:

755nm laser:

Temporary hair reduction.

Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I – VI) including tanned skin.

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550-1200nm	Skin Types I, II	-	-	Skin Type III
600-1200nm	Skin Type III	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

Substantial equivalence discussion:

The DEKA Synchro Repla:Y family of laser systems is substantially equivalent to the DEKA Synchro Repla:Y family of laser systems (K131095).

Device Trade Name	DEKA Synchro Repla:Y family of laser systems	Predicate Device K131095 DEKA Synchro Repla:Y family of laser systems
Laser Type	Alexandrite, Nd:YAG	Alexandrite, Nd:YAG
Wavelength	755 nm, 1064 nm	755 nm, 1064 nm
Max Fluence	600 J/cm ²	600 J/cm ²
Spot Sizes	2.5 to 24mm	2.5 to 20mm
Pulse Duration	0.25 to 300 ms	0.25 to 300 ms
Pulse Rep Rate	up to 10 Hz	up to 10 Hz
Skin Cooling System	Yes, optional	Yes, optional

Device Trade Name	DEKA Synchro Repla:Y family of laser systems	Predicate Device K131095 DEKA Synchro Repla:Y family of laser systems
Device Type	Pulsed Flashlamp	Pulsed Flashlamp
Wavelengths (nm)	500 - 1200nm 520 - 1200nm 550 - 1200nm 600 - 1200nm 650 - 1200nm	500 - 1200nm 520 - 1200nm 550 - 1200nm 600 - 1200nm 650 - 1200nm
Pulse Width	3 – 124 ms	3 – 124 ms
Fluence	3 - 25 J/cm ²	3 - 25 J/cm ²
Repetition Rate	0.5 Hz max.	0.5 Hz max.
Spot Sizes	48x13 mm	48x13 mm
Method of Skin Cooling	Integrated - provided via the handpiece lightguide	Integrated - provided via the handpiece lightguide
Method of Output	Direct Delivery Handpiece	Direct Delivery Handpiece

The DEKA Synchro Repla:Y family of laser systems has the same indications for use as the abovementioned predicate device, with same principle of operation and essentially the same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

None

Conclusion:

The Deka Synchro Repla:Y family of laser systems is a family of safe and effective devices for the applications mentioned above.

Additional Information:

None